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09/887,953	06/22/2001	Varouj Amirkhanian	1031/205	7677

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EXAMINER

COUNTS, GARY W

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/02/2002 7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/887,953

Applicant(s)

AMIRKHANIAN, VAROUJ

Examiner

Gary W. Counts

Art Unit

1641

-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

The amendment filed September 19, 2002 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 7, lines 3-8 of the specification. The applicant discloses that the zone for optical detection of sample components is located at a widened zone along the separation channel. And that the widened detection zone is a micro-bore collar having a micro-channel that coaxially surrounds the exit of a capillary column that defines a capillary channel. On pages 16, line 18 – page 17, line 5 in the specification. The applicant discloses that as the analytes flow from the separation channel 504 of capillary column 22 into the collar 10, the analytes remain subject to the applied potential. As a result, the analytes continue to maintain separation state as they migrate/flow past the detection zone 20. Some mixing or diffusion of the analytes may occur in the collar near the exit of the separation channel 504, but analytes “regroup” into separated state as they continue down along

Art Unit: 1641

the collar 10 towards the detection zone 20. The detection zone 20 is preferably located at 100 x 500 ID of the collar, more like 225 times ID, to provide sufficient distance for the analytes to regroup before detection at the detection channel 504, the analyte bands are narrower in the axial direction. Thus the detection resolution may be improved as a result. The applicant does not disclose a transition from the first width to the second width. There is no description in the specification disclosing a transition from the first width to the second width.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 4 "the first width" there is insufficient antecedent basis for this limitation. See also deficiencies found in claim 16, part (a).

Claim 1, line 4 "a transition" is vague and indefinite. It is unclear what applicant is referring to. There is no definition provided for the term in the specification. See also deficiencies found in claim 16, part (a).

Claim 21, line 6 "close proximity" is vague and indefinite. It is unclear what is considered to be proximate. There is no definition of the recitation "close proximity" provided in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al (Axial-Beam Laser-Excited Fluorescence Detection in Capillary Electrophoresis, Anal Chem. 1992, 64, 1741-1744).

Taylor et al disclose a detection system for axial-beam laser excited fluorescence detection in capillary electrophoresis. Taylor et al disclose the use of a fiber optic which focuses the excitation laser beam which directs the light along the capillary rather than across it (col 1, page 1741, lines 1-27). Taylor et al also disclose that this fiber is directed into an end of the detection section in proximity to the detection zone (col 1, page 1742, lines 8-10). Taylor et al also disclose the use of cladding material and a jacket which surround the fiber for guiding the excitation radiation from the excitation source to the detection zone (col 2, page 1741, lines 12-18). Taylor et al also disclose a means for detecting radiation emission from the detection zone (col 1, page 1742, lines 22-39).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1641

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 10 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu et al (US 5,763,277).

Zhu et al disclose a detection system which comprises a capillary tube (col 6, line 46) used for electrophoresis (separation channel) (col 2, lines 49-51). Zhu et al disclose that sample analyte fluorescence is caused to occur by the application of energy (excitation radiation) to sample analytes caused to be present within the system (col 2, lines 62-65, see also figure 1). Zhu et al disclose the use of an axially oriented fiber optic which is directed into an end of the detection section in proximity to the detection zone. Zhu et al disclose that this fiber optic transmits the produced fluorescence (radiation emission) to a detector system (col 3 lines 1-6, see also figure 1). Zhu et al also disclose that the inner diameter of the axially oriented system component is increased at the location of contained axially oriented fiber optic means (col 5, lines 1-3).

With respect to a transition as recited in the instant claims Zhu et al disclose an exit from a small diameter (first width) to a larger diameter (second width) (see figure 3). Therefore, Zhu et al disclose a transition from a first width to the second width.

With respect to the detection section defining a detection zone at a distance of 100 to 500 times the second width from the transition as recited in the instant claims, the optimum distance of the second width from the transition can be determined by routine experimentation

Art Unit: 1641

and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of *Aller*, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of *Boesch*, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

Claims 3, 4 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu et al (US Patent 5,763,277) in view of Taylor et al (Axial-beam Laser-Excited Fluorescence Detection In Capillary Electrophoresis, Anal. Chem. 1992, Vol. 64, 1741-1744).

See above for teachings of Zhu et al.

Zhu et al differ from the instant invention in failing to teach a means for introducing excitation radiation axially at the detection zone. Zhu et al also fails to teach a boundary material that surrounds the light emitting material for guiding the excitation radiation from the excitation source to the detection zone.

Taylor et al disclose the use of an optical fiber which focuses the excitation laser beam which directs the light along the capillary rather than across it. Taylor et al also disclose that this fiber is inserted into the separation capillary (col 1, page 1742, lines 6-10). The use of this optical fiber allows for axial-beam fluorescence excitation which provides the added advantage of very little scattered light originating from the capillary

Art Unit: 1641

walls which allows the use of capillaries with intact polyamide coatings without problems of interference due to absorption or greatly increased fluorescence background. It also provides for a longer absorption path length compared to irradiation across the capillary (col 1, page 1741, lines 35-47). Taylor et al also disclose the use cladding material and a jacket which surround the fiber for guiding the excitation radiation from the excitation source to the detection zone.

It would have been obvious to one of ordinary skill in the art to incorporate the use of a fiber and a surrounding material as taught by Taylor et al into the detection system of Zhu et al because Taylor et al shows that the use of this fiber and surrounding material allows for axial-beam fluorescence excitation which provides the added advantage of very little scattered light originating from the capillary walls which allows for the use of capillaries with intact polyamide coatings without problems of interference due to absorption or greatly increased fluorescence background. It also provides for a longer absorption path length compared to irradiation across the capillary.

With respect to the light transmitting material having a refractive index greater than the refractive index of the boundary material as recited in the instant claims. It would have been obvious to one of ordinary skill in the art to incorporate a light transmitting material which has a refractive index greater than the refractive index of the boundary material because this would allow one to maintain the light with the fiber optic so that loss of the intensity of the light would not occur.

Art Unit: 1641

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu et al (US Patent 5,763,277) in view of Taylor et al as applied to claims 1-4, and 10-18 above, and further in view of Letcher et al (US Patent 6,326,213).

See above for teachings of Zhu et al and Taylor et al.

Zhu et al differ from the instant invention in failing to teach the means for axially detecting radiation emission shares the same single fiber as the means for introducing excitation radiation axially to transmit excitation radiation and radiation emission.

Letcher et al disclose a single step-taperd fiber used for excitation and detection (col 3, lines 1 and 2, see also abstract). The use of this fiber allows for enhancement of the sensitivity of a fiber-optic biosensor using fluorescent immunoassay techniques for the rapid detection of a pathogen.

It would have been obvious to one of ordinary skill in the art to incorporate the fiber of Letcher et al into the detection system of Zhu et al because Letcher et al shows that the used of this fiber allows for enhancement of the sensitivity of a fiber-optic biosensor using fluorescent immunoassay techniques for the rapid detection of a pathogen.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu et al, in view of Taylor et al and Letcher et al as applied to claims 1-5 and 10-18 above, and further in view of Hazman et al (US Patent 5,625,403).

See above for teachings of Zhu et al, Taylor et al, and Letcher et al.

Zhu et al differ from the instant invention in failing to disclose a confocal optical element that transmits excitation radiation and radiation emission.

Art Unit: 1641

Hazman et al disclose the use of a dichroic beam combiner along with a set of lens. This dichroic beam combiner is used to selectively reflect and transmit light according to its wavelength (col 4, lines 30-33). The use of the beam combiner and set of lens allows for the combination of laser beams and enabling the realization of a practical high power optical head.

It would have been obvious to one of ordinary skill in the art to incorporate the beam combiner and set of lens as taught by Hazman et al into the detection system of Zhu et al because Hazman et al shows that the use of the beam combiner allows for selectivity of light reflection and transmission according to its wavelength and the beam combiner and set of lens also allows for the combination of laser beams and enabling the realization of a practical high power optical head.

Response to Arguments

Applicant's arguments filed September 19, 2002 have been fully considered but they are not persuasive.

Applicant argues that the Zhu et al reference is silent in the written disclosure as to the location of the detection zone and the distance from the transition. This is not found persuasive because the optimum distance of the detection zone can be determined by routine experimentation.

Applicant argues that the Zhu et al reference shows the fiber optic 3 inserted into the increased inner diameter (1d) of the bore 2, with the tip within 1 time of the increased diameter 1d from the transition from the smaller diameter. It is unclear to

Art Unit: 1641

examiner where the disclose of the tip is within 1 time of the increased diameter 1d is disclosed in the Zhu et al reference.

Applicant argues that the Zhu et al reference did not address the concern with mixing and diffusion and regrouping of analyte back into separated state. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., mixing and diffusion and regrouping of analyte back into separated state) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that the Taylor reference is not directed to axial detection of emitted radiation from the detection zone. . This is not found persuasive because examiner has not relied upon the Taylor et al reference for this limitation, but rather for the limitation of introducing excitation radiation axially at the detection zone.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1641

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Application/Control Number: 09/887,953

Page 12

Art Unit: 1641


Gary W. Counts

Examiner

Art Unit 1641

October 1, 2002



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SUPERVISORY PATENT EXAMINER
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10/01/02